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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,223	12/27/2000	Robert H. Daniels	5100-0005	6599

23419 7590 07/07/2003

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/07/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/750,223

Applicant(s)

DANIELS ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

The amendment and declaration filed April 28, 2003 is acknowledged and has been entered.

Rejections Maintained

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 10, 11, 13-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al (US 6,352,862) in view of Bruchez et al (US 6,274,323).

Davis et al disclose quantitative and qualitative methods for determining an analyte of interest. Davis et al disclose applying the sample to a test strip which comprises an aperture (Figure 4, (401))(sample reservoir). Davis et al disclose a chromatographic strip such as a strip of nitrocellulose. Davis et al disclose a labeled specific binding reagent in the dry state which binds the analyte (col 2, lines 4-15). Davis et al disclose that this label can be any entity the presence of which can be readily detected (col 6, lines 42-53). Davis et al disclose an unlabelled specific binding reagent, which is permanently immobilized (capture reagent) in a detection zone on the strip. Davis et al disclose that the labeled and unlabelled reagents participate in a sandwich reaction in the presence of the analyte (col 1, lines 53-67). Davis et al also

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disclose a control zone which comprises an immobilized antibody that will bind to the labeled reagent. Davis et al disclose that the control zone is located downstream of the detection zone (col 6, lines 23-41). Davis et al disclose that the test strip has a first end and a second end and the sample reservoir is located at the first end and the sample mixture flows from the first end to the second end. Davis et al also disclose exposing the test strip to a light source to determine the presence of the analyte in the test sample (col 6, line 42- col 7, line 29).

Davis et al differ from the instant invention in failing to disclose the first detection ligand is conjugated with a semiconductor nanocrystal.

Bruchez et al disclose semiconductor nanocrystals as detection reagents in immunoassays. Bruchez et al disclose that when semiconductor nanocrystals are irradiated with an energy source, such as an excitation light source. The semiconductor nanocrystal emits a characteristic emission spectrum, which can be observed and measured (col 4, lines 43-61). Bruchez et al disclose that these semiconductor nanocrystals can be couple to antibodies (col 23). Bruchez et al also disclose that the specific-binding molecule may comprise a nucleic acid molecule (col 8, lines 1-10). Bruchez et al disclose that these coupled semiconductor nanocrystals can be used in solid phase assays (col 25 lines 43-67). Bruchez et al disclose that these semiconductor nanocrystal labels provide (i) high fluorescent intensity, (ii) adequate separation between the absorption and emission frequencies, (iii) good solubility, (iv) ability to be readily linked to other molecules, (v) stability towards harsh conditions and high temperatures, (vi) a symmetric, nearly gaussian emission lineshape for easy

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deconvolution of multiple colors, and (vii) compatibility with automated analysis. And at present time, none of the convention fluorescent labels satisfy all of the requirements.

It would have been obvious to one of ordinary skill to incorporate semiconductor nanocrystals as taught by Bruchez et al into the method of Davis et al because Bruchez et al shows that these semiconductor nanocrystal labels provide (i) high fluorescent intensity, (ii) adequate separation between the absorption and emission frequencies, (iii) good solubility, (iv) ability to be readily linked to other molecules, (v) stability towards harsh conditions and high temperatures, (vi) a symmetric, nearly gaussian emission lineshape for easy deconvolution of multiple colors, and (vii) compatibility with automated analysis. And at present time, none of the convention fluorescent labels satisfy all of the requirements.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al and Bruchez et al in view of Bawendi et al (US 6,444,143).

See above for teachings of Davis et al and Bruchez et al.

Davis et al and Bruchez et al differ from the instant invention in failing to teach a microsphere conjugated directly to the detection ligand, wherein the microsphere is dyed with the semiconductor nanocrystals.

Bawendi et al disclose quantum dots (semiconductor nanocrystals) coupled to beads (microspheres) (col 11, lines 30-40. Bawendi et al disclose that these quantum dots coupled to beads provides the advantage of tracking or identifying an article of interest.

It would have been obvious to one of ordinary skill in the art to incorporate quantum dots coupled to beads as taught by Bawendi et al into the modified method of Davis et al and Bruchez et al because Bawendi et al teaches that these quantum dots coupled to beads provides the advantage of tracking or identifying an article of interest.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al and Bruchez et al in view of Bawendi et al as applied to claims 1-7, 10, 11, 13-15 and 17-19 above and further in view of Weiss et al (US 5,990,479).

See above for teachings of Davis et al, Bruchez et al and Bawendi et al.

Davis et al, Bruchez et al and Bawendi et al differ from the instant invention in failing to teach the nanocrystals are contained within the interior of the microsphere.

Weiss et al disclose glass coated semiconductor nanocrystals (microsphere). Weiss et al disclose that the nanocrystal is within the glass particle (col 7, lines 6-63). Weiss et al disclose that the use of such microspheres provide for the detection of one or more detectable substances in organic materials, and in particular to the detection of one or more detectable substances in biological materials.

It would have been obvious to one of ordinary skill in the art to incorporate microspheres as taught by Weiss et al into the modified method of Davis et al and Bruchez et al because Weiss et al shows that the use of such microspheres provide for the detection of one or more detectable substances in organic materials, and in particular to the detection of one or more detectable substances in biological materials.

Claims 12, 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al and Bruchez et al in view of Bawendi et al (US 6306,610).

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See above for teachings of Davis et al and Bruchez et al.

Davis et al and Bruchez et al differ from the instant invention in failing to teach the protein is an enzyme.

Bawendi et al disclose binding pairs used in quantum dot assays. Bawendi et al disclose exemplary binding pairs such as enzyme-enzyme cofactor and enzyme-enzyme-inhibitor (col 6, line 51 – col 7, line 7). The use of such exemplary binding pairs provide first and second molecules that specifically bind to each other with greater affinity and specificity than to other components in the sample.

It would have been obvious to one of ordinary skill in the art to incorporate the use of enzymes as taught by Bawendi et al into the modified method of Davis and Bruchez et al in order to provide first and second molecules that specifically bind to each other with greater affinity and specificity than to other components in the sample.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al and Bruchez et al in view of Lee et al.

See above for teachings of Davis et al and Bruchez et al.

Davis et al and Bruchez et al differ from the instant invention in failing to teach the control ligand is a nucleic acid molecule.

Lee et al disclose the ligand or control reagent may be a protein, peptide, amino acid, nucleic acid or hormone (col 6, line 59 – col 7 line7).

It would have been obvious to one of ordinary skill in the art to incorporate a nucleic acid as taught by Lee et al into the modified method of Davis et al and Bruchez et al because it would provide a molecule to which a molecule of interest will bind.

Response to Arguments

Applicants arguments and the declaration filed April 28, 2003 have been fully considered but they are not found persuasive.

Applicant argues that Bruchez is not properly citable art against the present claims and that in particular, Bruchez and the present application include an inventor in common, Robert H. Daniels (Examiner interprets Robert H. Daniels, listed on the declaration and application and R. Hugh Daniels listed on US Patent 6,274,323 to be one and the same person) and the unclaimed subject matter in Bruchez, directed to the present invention is attributable to the inventors in the present application. Applicant relies on the Declaration filed April 28, 2003 (paper no. 11) to overcome the Bruchez et al reference. Applicant relies on the statement on page 1, section 2 stating "We do not believe that Marcel P. Bruchez, Stephen A. Empedocles, Vince E. Phillips, Edith Y. Wong and Donald A. Zehnde, who are co inventors on U.S. Patent No. 6.274,323 and are not named as inventors on the present application, conceived of methods for determining the presence of an analyte in a test sample using a test strip as claimed in the present application". This is not found persuasive because Applicant has not provided a statement establishing that the relevant portion of the Bruchez reference relied upon by the Examiner (the advantages of using conjugated nanocrystals as detection reagents in immunoassays) originated with the applicant and that the disclosure was derived from him and not the other co-inventors. Further, the applicant has not affirmatively established that he had made the invention upon which the Bruchez reference disclosure is based. Furthermore, the Examiner has not relied upon

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Bruchez et al for teaching determining the presence of an analyte in a test sample using a test strip, but rather has relied upon Davis et al for this teaching. Examiner has relied upon Bruchez et al for teaching the advantages of using conjugated nanocrystals as detection reagents in immunoassays.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts
Examiner
Art Unit 1641
July 1, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
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07/05/03